Supreme Court, U.S.
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No.

IN THE
Supreme Court of the United States

R & F PROPERTIES OF LAKE COUNTY, INC.,
F/K/A LEESBURG FAMILY MEDICINE,
Petitioner,

v.

UNITED STATES OF AMERICA *EX. REL* KARYN L. WALKER,
Respondent.

ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

APPENDIX TO THE PETITION FOR A WRIT OF CERTIORARI

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TABLE OF CONTENTS

Page

Appendix A (court of appeals opinion, filed Dec. 30, 2005) 1a

Appendix B (district court order, filed Oct. 6, 2004) 20a

Appendix C (court of appeals order denying rehearing and rehearing en banc, filed Mar. 31, 2006) 37a

Appendix D (Constitutional, statutory, and regulatory provisions) 38a

Appendix A

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 04-15283

D.C. Docket No. 02-00131-CV-OC-10-GRJ

UNITED STATES, ex rel.,

Plaintiff,

KARYN L. WALKER,
a.k.a. Karyn L. Denk-Walker,

Plaintiff-Appellant
Cross-appellee

versus

R & F PROPERTIES OF LAKE COUNTY, INC.,
A Florida Professional Association,

Defendant-Appellee
Cross-Appellant.

Appeals from the United States District Court
for the Middle District of Florida

(December 30, 2005)

Before BIRCH, WILSON and COX, Circuit Judges.

COX, Circuit Judge:

Plaintiff Karyn L. Walker is a *qui tam* relator, seeking recovery on behalf of the United States pursuant to the False Claims Act, 31 U.S.C. § 3729. Walker appeals a summary judgment granted to Defendant R&F Properties of Lake County, Inc., formerly known as Leesburg Family Medicine, (LFM). And Walker contends that the district court erred in limiting the scope of information discoverable in the case to that information relevant to the time period during which she was employed by LFM as a nurse practitioner. LFM cross-appeals, contending that the district court erred in denying its motion to dismiss Walker's Amended Complaint.

We conclude that the district court erred in holding that Walker had not produced sufficient evidence of the falsity of the claims submitted by LFM to resist summary judgment. Therefore, we reverse the district court's judgment. We also find error in the district court's order limiting discovery. We find no error in the district court's denial of LFM's motion to dismiss.

I. BACKGROUND & PROCEDURAL HISTORY

The Medicare Program is a system of health insurance administered by the United States Department of Health and Human Services, through the Center for Medicare and Medicaid Services (CMS). CMS was formerly known as the Health Care Financing Administration (HCFA). Medicare Part B is a federally subsidized, voluntary health insurance program that pays a portion of the costs of certain health services, including the costs of clinic visits to healthcare providers (among them, physicians, physician assistants, and nurse practitioners). Reimbursement for Medicare Part B claims is made through CMS, which contracts with private insurance carriers throughout the United States to administer and pay claims within their regions from the Medicare Trust Fund. These insurance carriers are known as Fiscal Intermediaries, or FIs. In general, when a healthcare service

is rendered to a patient covered by Medicare Part B, the healthcare provider bills Medicare/CMS through the FI. The FI reviews the bill and pays the healthcare provider. CMS publishes a series of manuals that provide billing and payment instructions to the Medicare community. Among these manuals are the Medicare Carrier's Manual, directed to the FIs, and the Provider Reimbursement Manual, directed to healthcare providers.

LFM operates medical clinics in Leesburg and Lady Lake, Florida. At these clinics, physicians, physician assistants, and nurse practitioners provide medical services to the community. Many, if not most, of LFM's patients are covered by Medicare Part B. LFM submits claims for Medicare reimbursement for healthcare services rendered by physicians, physician assistants and nurse practitioners to its FI, Blue Cross Blue Shield of Florida, pursuant to a contract between LFM and Blue Cross Blue Shield. These claims are made on HCFA 1500 forms in electronic form, as required by the Medicare regulations, and signed electronically by LFM's physicians. Each HCFA 1500 form states:

> SIGNATURE OF PHYSICIAN OR SUPPLIER
> (MEDICARE, CHAMPUS, FECA AND
> BLACK LUNG)
>
> I certify that the services shown on this form were medically indicated and necessary for the health of the patient and were personally furnished by me or were furnished incident to my professional service by my employee under my immediate personal supervision, except as otherwise expressly permitted by Medicare or CHAMPUS regulations.
>
> For services to be considered "incident" to a physician's professional service, 1) they must be rendered under the physician's immediate personal

> supervision by his/her employee, 2) they must be an integral, although incidental part of a covered physician's service, 3) they must be of kinds commonly furnished in physician's offices, and 4) the services of nonphysicians must be included on the physician's bills.

(R.2-79 Ex. G.)

Healthcare providers may bill Medicare Part B for the services of physician assistants and nurse practitioners in one of two ways; the amount of reimbursement the providers receive is dependent on the billing method. Physician assistant or nurse practitioner services may be billed as services "incident to the service of a physician." 42 CFR §§ 410.10, 410.26. To be correctly billed in this manner, the physician assistant or nurse practitioner services must have been provided under certain circumstances.[1] When physician assistant or nurse practitioner services are billed as "incident

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[1] For the relevant time period prior to January 1, 2002, 42 CFR § 410.26 stated:

> (a) Medicare Part B pays for services and supplies incident to a physician's professional services, including drugs and biologicals that cannot be self-administered, if the services or supplies are of the type that are commonly furnished in a physician's office or clinic, and are commonly furnished either without charge, or included in the physician's bill.

Effective January 1, 2002, 42 CFR § 410.26 was amended to read, in relevant part:

> (b) Medicare Part B pays for services and supplies incident to the service of a physician (or other practitioner).
>
> (1) Services and supplies must be furnished in a noninstitutional setting to noninstitutional patients.

to the service of a physician," the physician's Unique Provider Identification Number (UPIN) is used on the bill submitted to the FI. Alternatively, a provider may bill Medicare for physician assistant and nurse practitioner services under the physician assistant's or nurse practitioner's own UPIN. Billing Medicare in this second way indicates that the physician assistant or nurse practitioner has performed the service under some level of supervision by a physician, but the requirements of 42 CFR § 410.26 have not necessarily been met. For services billed under a physician assistant's or

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> (2) Services and supplies must be an integral, though incidental, part of the service of a physician (or other practitioner) in the course of diagnosis or treatment of an injury or illness.
>
> (3) Services and supplies must be commonly furnished without charge or included in the bill of a physician (or other practitioner).
>
> (4) Services and supplies must be of a type that are commonly furnished in the office or clinic of a physician (or other practitioner).
>
> (5) Services and supplies must be furnished under the direct supervision of the physician (or other practitioner). The physician (or other practitioner) directly supervising the auxiliary personnel need not be the same physician (or other practitioner) upon whose professional service the incident to service is based.

. . .

"Direct supervision," as used in 42 CFR § 410.26, is defined by reference to 42 CFR § 410.32(b)(3)(ii), a provision that, since 1998, states:

> *Direct supervision* in the office setting means the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed.

nurse practitioner's UPIN, the FI pays 85% of what it would pay for the same services billed under a physician's UPIN.

Walker worked for LFM from February 1997 until May 1999 as a nurse practitioner. During that time, there were many occasions when she saw patients independently without physician supervision. Physicians were not always physically present in the LFM clinic while Walker and other nurse practitioners and physician assistants saw patients, but physicians were always available for consultation by pager and telephone.

II. CONTENTIONS OF THE PARTIES

Walker brings this suit as a *qui tam* relator under the False Claims Act. She alleges that LFM filed false claims for Medicare reimbursement by billing Medicare for services rendered by nurse practitioners and physician assistants as if those services were rendered "incident to the service of a physician," even though LFM knew that the nurse practitioner and physician assistant services did not meet several of the criteria necessary for billing in that manner. Chief among Walker's complaints is that LFM billed all nurse practitioner and physician assistant services as "incident to the service of a physician," even though the nurse practitioners and physician assistants often treated patients at LFM's clinics when no physician was physically present in the clinic. She contends that a physician's physical presence within the office suite was required in order for the nurse practitioner's or physician assistant's service to have been rendered "incident to the service of a physician," as used in 42 CFR § 410.26 and "under the physician's immediate personal supervision" as certified by the physician on each HCFA 1500 claim form. Walker further contends that LFM knew that its billing practice was fraudulent and that LFM knew the proper way to bill the services (as services rendered directly by the nurse practitioner or physician assistant rather than as services

"incident to the service of a physician"). Walker alleges that, as a result of the fraudulent manner in which LFM billed Medicare, LFM was paid 15% more than it should have been paid for nurse practitioner and physician assistant services to Medicare patients.

LFM admits that physicians were not always physically present in the clinic while nurse practitioners and physician assistants treated patients. LFM also admits that it submitted HCFA 1500 forms to Blue Cross Blue Shield requesting Medicare reimbursement for services of nurse practitioners and physician assistants performed "incident to the service of a physician," even if the nurse practitioner and physician assistant services were performed while no physician was physically present in the LFM office suite. LFM further concedes that the submission of the HCFA 1500 forms constitutes the presentation of claims for purposes of the False Claims Act. However, LFM argues that, as a matter of law, these claims could not have been false within the meaning of the False Claims Act because the phrase "incident to the service of a physician" was, at least until January 1, 2002, vague and subject to reasonable interpretations other than that championed by Walker. It further argues that the "immediate personal supervision" language in the HCFA 1500 certification is similarly vague and therefore, as a matter of law, cannot be the basis for a false claim.

The parties also disagree about the time period relevant to Walker's lawsuit. Walker maintains that LFM made false claims for physician assistant and nurse practitioner services performed from the time it first hired a physician assistant in 1994 through the date Walker filed her complaint, and she argues that her complaint properly alleges the existence of false claims throughout this entire period. LFM, on the other hand, contends that Walker could allege properly only that

false claims were presented from February 1997 through May 1999, the dates of her employment at LFM.[2]

The district court granted LFM summary judgment because it found that LFM's requests for reimbursement could not be false as a matter of law. The district court reasoned that, because the Medicare statutes and regulations in effect during the period of Walker's employment with LFM did not adequately define the phrase "incident to the service of a physician" and because the terms "immediate," "integral," and "incidental" as used on the HCFA 1500 form "are inherently imprecise," LFM's interpretation of the terms (that nurse practitioners and physician assistants could see patients independently so long as a physician was available by pager and telephone) must be accepted as reasonable. In opposition to LFM's motion for summary judgment, Walker offered evidence of how the regulatory language and the HCFA 1500 certification language were interpreted in the Medicare community. Walker contends that this evidence would support a finding that the claims submitted were false. However, the district court considered the evidence insufficient to present an issue of fact as to the meaning of the terms.

III. ISSUES ON APPEAL

To determine whether the district court erred in granting summary judgment, we must decide whether the Medicare regulations and HCFA 1500 form are unclear regarding the criteria that must be fulfilled in order for services of a nurse

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[2] According to LFM, however, this is a hypothetical. LFM contends that Walker's Amended Complaint does not properly plead any cause of action regarding any time period and that it should have been dismissed by the district court because it is not specific enough to satisfy the pleading requirements of Federal Rule of Civil Procedure 9(b).

practitioner or physician assistant to be billed as services "incident to the service of a physician." If we decide that they are unclear, we must then decide whether a court may look to evidence other than the language of the regulation and form to determine whether a claim, allegedly submitted in violation of that language, is false within the meaning of the False Claims Act. If we decide that a court may look to evidence outside the language at issue, we must determine whether the evidence Walker presented in opposition to LFM's motion for summary judgment is sufficient to create an issue of fact as to the falsity of the claims LFM made to Medicare.

We also decide whether the district court erred in limiting discovery in the action to information relevant to the time period during which Walker was employed by LFM.

Finally, to decide LFM's cross-appeal, we determine whether Walker's Amended Complaint satisfies the requirements of Rule 9(b).

IV. STANDARDS OF REVIEW

We review the district court's grant of summary judgment de novo, applying the same legal standards that bound that court and "viewing all facts and reasonable inferences in the light most favorable to the nonmoving party." *Strickland v. Water Works and Sewer Bd. of the City of Birmingham*, 239 F.3d 1199, 1203 (11th Cir. 2001). Summary judgment is appropriate when "there is no genuine issue as to any material fact and . . . the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c).

The district court's discovery decisions are reviewed for abuse of discretion. *See Burger King Corp. v. Weaver*, 169 F.3d 1310, 1315 (11th Cir. 1999).

We review de novo the denial of a motion to dismiss. *See Nolen v. Jackson*, 102 F.3d 1187, 1190 (11th Cir. 1997).

V. DISCUSSION

The False Claims Act states:

> Any person who . . . knowingly presents, or causes to be presented, to an officer or employee of the United States Government . . . a false or fraudulent claim for payment or approval . . . is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person. . . .

31 U.S.C. § 3729(a). The False Claims Act authorizes private citizens to bring actions on behalf of the United States. 31 U.S.C. § 3730(b). These plaintiffs are known as *qui tam* relators. To establish a cause of action under the False Claims Act, a relator must prove three elements: (1) a false or fraudulent claim; (2) which was presented, or caused to be presented, by the defendant to the United States for payment or approval; (3) with the knowledge that the claim was false. 31 U.S.C. § 3729(a). Recovery under the False Claims Act is not measured by the amount of any actual damage a relator might have sustained personally as a result of a defendant's false claim. Rather, the relator stands in the shoes of the United States government. She can prosecute the lawsuit on the United States' behalf, and recover, for the United States, the losses attributable to any fraudulent claim and the civil penalty authorized by the statute. 31 U.S.C. § 3730.

A. The Grant of Summary Judgment

In this case, the district court granted summary judgment for LFM because it found that, as a matter of law, Walker's complaint and evidence did not present the possibility of a false or fraudulent claim. As stated above, the district court found that the regulatory language that Walker claimed was

violated when LFM submitted its claims was ambiguous and therefore could not, as a matter of law, serve as the predicate for a false claims action. We find error in the district court's reasoning.

First, we note that the district court granted LFM summary judgment on Walker's entire complaint even though a subset of the claims alleged by Walker were allegedly submitted after the Medicare regulation had been amended and clarified. *See supra* n.1. As of January 1, 2002 (four months before Walker filed her original complaint in this case), the regulation providing conditions for coverage of services rendered "incident to the service of a physician" was clear about the meaning of that phrase. As of that date, all services billed as "incident to the services of a physician" must have been rendered under a physician's "direct supervision." 42 CFR § 410.26(b)(5) (2002). In order to satisfy this "direct supervision" requirement, "the physician must [have been] present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure." 42 CFR § 410.26(a)(2) (2002), 410.32(b)(3)(ii) (2002). This regulatory language unambiguously requires that a physician be present in the office. Furthermore, this new regulatory language illuminates the meaning of the physician certification on the HCFA 1500 form that the billed services "were personally furnished by me or were furnished incident to my professional service by my employee under my immediate personal supervision," at least as of January 1, 2002.

Medicare claims may be false if they claim reimbursement for services or costs that either are not reimbursable or were not rendered as claimed. *See United States v. Calhoon*, 97 F.3d 518, 524 (11th Cir. 1996); *Peterson v. Weinberger*, 508 F.2d 45, 52 (5th Cir. 1975). Given the clear definition of services rendered "incident to the service

of a physician" that became effective January 1, 2002, Walker should be permitted to present evidence to a fact-finder supporting her allegations that any Medicare claims LFM submitted from January 1, 2002 until the date of her complaint for services of nurse practitioners or physician assistants "incident to the service of a physician," were not, in fact, rendered in compliance with the applicable Medicare regulation and, therefore, were false. An issue of fact also exists as to whether LFM physician certifications on the HCFA 1500 forms submitted from January 1, 2002 until the date of Walker's complaint were false.

Additionally, the district court erred by holding that any ambiguity in the earlier version of 42 CFR § 410.26 and the HCFA 1500 certification necessarily forecloses, as a matter of law, the falsity of claims submitted by LFM prior to January 1, 2002. We agree that the regulatory language in effect until January 1, 2002 was ambiguous. But we disagree as to the legal significance of that ambiguity. In opposition to LFM's motion for summary judgment, Walker submitted provisions from the Medicare Carrier's Manual, Medicare bulletins, seminar programs, and expert testimony regarding proper billing "incident to the service of a physician," as used in 42 U.S.C. § 410.26. She also presented two notes written by LFM's employee that paraphrase a billing consultant's advice. All of these sources were offered to show the meaning of the language in the regulation and on the HCFA 1500 form and the reasonableness of LFM's claimed understanding of that language. At least some of these sources would support a finding that, in the Medicare community, the language was understood to mean that a physician had to be physically present in the office suite and otherwise more involved in a patient's course of care than the LFM physicians were. The district court considered this evidence irrelevant and held that, because none of it held the force of law, it could not be the basis for a false claim.

As the district court recognized, the Supreme Court has stated that agency interpretations contained in policy statements, manuals, and enforcement guidelines are not entitled to the force of law. *Christensen v. Harris County*, 529 U.S. 576, 587, 120 S. Ct. 1655, 1662 (2000). For that reason, we agree with the district court that evidence of a defendant's failure to comply with an administrative guideline does not necessarily establish that the defendant presented legally false claims–claims in violation of a statute or regulation–to the United States. But that is not the issue here. What is at issue is whether any evidence outside the language of a Medicare regulation (including guidance issued by the governmental agency charged with administering the regulatory scheme) can be consulted to understand the meaning of that regulation. We hold that it can.

The Supreme Court has held that agency interpretations are "entitled to respect . . . to the extent that those interpretations have the power to persuade." *Id.*, 120 S. Ct. at 1663 (citing *Skidmore v. Swift & Co.*, 323 U.S. 134, 140, 65 S. Ct. 161, 164 (1944)). Our precedent is consistent. Indeed, we have followed this rule in the context of Medicare false claims cases. In affirming a criminal false claims conviction, this court looked to a manual published by HCFA to determine the meaning of a Medicare regulation and establish the falsity of the defendant's claims for Medicare reimbursement. *See Calhoon*, 97 F.3d at 526 (consulting the Provider Reimbursement Manual to define the meaning of a phrase in the Medicare regulations). The fact that the Medicare Carrier's Manual was not issued to Defendants does not negate its probative value regarding the meaning of a Medicare regulation. *See United States v. Gold*, 743 F.2d 800, 816 (11th Cir. 1984) (affirming criminal conviction of eye doctor for Medicare fraud and approving admission of Medicare Carrier's Manual provisions as evidence of what types of claims were properly payable under Medicare).

In a case remarkably similar to this one, the Eighth Circuit recently held, "If a statement alleged to be false is ambiguous, the government (or here, the relator) must establish the defendant's knowledge of the falsity of the statement, which it can do by introducing evidence of how the statement would have been understood in context." *Minnesota Assoc. of Nurse Anesthetists v. Allina Health System Corp.*, 276 F.3d 1032, 1053 (8th Cir. 2002) (emphasis added). In the Minnesota case, the relator alleged that anesthesiologists billed Medicare as if they had "personally performed" an entire anesthesia case or were "continuously involved" in the performance of that case when, in fact, they were not continuously present during the case and were instead simultaneously engaged in other activities. *Id.* at 1037, 1038. A district court granted the defendants summary judgment because the court considered the Medicare regulation's phrases "personally performed" and "continuously involved" to be ambiguous. *Id.* at 1052-1053. The Eighth Circuit reversed, stating, "If the [relator] shows the defendants certified compliance with the regulation knowing that the HCFA interpreted the regulations in a certain way and that their actions did not satisfy the requirements of the regulation as the HCFA interpreted it, any possible ambiguity of the regulations is water under the bridge." *Id.* at 1053. The Eighth Circuit found that evidence presented by the relator (including the defendants' attorney's advice, HCFA memoranda, a bulletin published by the FI, and an American Society of Anesthesiologists newsletter) was relevant to a determination of the Medicare regulation's meaning and that there was a question of fact as to the defendants' understanding of the meaning of the regulatory language. *Id.* at 1053-54.

In opposition to LFM's motion for summary judgment, Walker presented provisions from the Medicare Carrier's

Manual in use during the relevant time period,[3] bulletins published by the FI (and received and maintained by LFM) that provide guidance on proper "incident to the service of a physician" billing, programs for seminars attended by LFM personnel that reviewed information on proper "incident to the service of a physician" billing, and copies of notes handwritten by LFM personnel documenting conversations between LFM administrative personnel and a billing consultant regarding the need for UPINs for physician assistants and nurse practitioners. Each of these pieces of evidence is relevant to the meaning of the Medicare

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[3] The parties agree that, throughout the time period relevant to this lawsuit (whatever that might be), the Medicare Carrier's Manual set forth five criteria for a service to be covered as "incident to the services of a physician." To be covered, a service must: (1) be an integral, although incidental, part of the physician's professional service; (2) be commonly rendered without charge or included in the physician's bill; (3) be of the type commonly furnished in physicians' offices or clinics; (4) be furnished under the direct personal supervision of a physician; and (5) be furnished by a physician or an employee of a physician. Medicare Carriers Manual Part 3, Claims Process Pub. 14-3 (MCM), § 2050, at 2-19.

The parties also agree that, since at least 1992, the MCM has defined "direct personal supervision in the office setting" to require that "the physician must be present in the office suite and immediately available to provide assistance and direction throughout the time the aide is performing services." MCM, § 2050.1.B. at 2-20.

The parties disagree, however, regarding the meaning of other language in the MCM, particularly the language in MCM, § 2050.2, that states "there must have been a direct, personal, professional service furnished by the physician to initiate the course of treatment of which the service being performed by the nonphysician practitioner is an incidental part, and there must be subsequent services by the physician of a frequency that reflects his or her continuing active participation in and management of the course of treatment." *Id.* at 2-21.

regulation at issue and LFM's understanding of that meaning. *See Gold*, 743 F.2d at 816 (Medicare Carrier's Manual and FI letter to provider properly admitted into evidence). Taken together, they are sufficient to support findings that the Medicare regulation required that a physician be physically present in the office suite and otherwise more involved in a patient's course of care than the LFM physicians were and that LFM knew of these requirements. Thus, they raise an issue of fact as to the falsity of LFM's billing for nurse practitioner and physician assistant services "incident to the service of a physician." Summary judgment was inappropriate.

B. The Limit on Discovery

Walker also challenges the district court's decision to limit discovery in the case to the date range of her employment as a nurse practitioner at LFM. She correctly states that, if, in limiting the temporal scope of discovery, the district court "made a clear error of judgment . . . or . . . applied an incorrect legal standard," we must reverse that decision. *Peat, Inc. v. Vanguard Research, Inc.*, 378 F.3d 1154, 1159 (11th Cir. 2004) (citing *Alexander v. Fulton County*, 207 F.3d 1303, 1326 (11th Cir. 2000)).[4]

We find that the district court misconstrued the False Claims Act when it limited discovery to the term of Walker's employment. We therefore reverse the discovery order. Under the False Claims Act, any person may serve as a *qui tam* relator. 31 U.S.C. § 3730(b). The relator need not have any relation at all to the defendant. *Id.* Neither is there a requirement that the relator suffer injury at the hands of the defendant in order to state a claim under the False Claims Act. *Id.* "The United States is the real party in interest in a qui tam

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[4] Walker raised this issue in her initial brief, but LFM did not respond or otherwise address the argument in any of its briefing.

action under the FCA even if it is not controlling the litigation." *United States ex rel. Dimartino v. Intelligent Decisions, Inc.*, 308 F.Supp. 2d. 1318, 1322 n.8 (M.D. Fla. 2004) (citing *United States ex rel. Rodgers v. Arkansas*, 154 F.3d 865, 868 (8th Cir.1998); *United States ex rel. Hyatt v. Northrop Corp.*, 91 F.3d 1211, 1217 n. 8 (9th Cir.1996); *United States ex rel. Milam v. University of Texas M.D. Anderson Cancer Center*, 961 F.2d 46, 48-49 (4th Cir.1992)).

Under the Federal Rules of Civil Procedure, discovery is limited to "matter[s], not privileged, that [are] relevant to the claim or defense of any party . . . . Relevant information need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence." Fed. R. Civ. P. 26(b)(1). Thus, Walker should have been permitted discovery of all information relevant to her claims, on behalf of the United States, that false claims for payment were made by LFM.

An examination of the Amended Complaint, the operative pleading in this case, demonstrates that Walker alleges that LFM submitted false claims from at least the time of Walker's hiring[5] into the undefined future. Paragraph 11 of the Amended Complaint recounts a conversation that Walker allegedly had with LFM's office manager, Gail Mayer. As part of that conversation, Mayer allegedly told Walker that LFM "never" billed nurse practitioner and physician assistant services as independent services but rather always billed them as services "incident to the service of a physician" and that if

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[5] Walker argues that discovery should be allowed from as far back as 1994, when LFM first hired a physician assistant (a fact that Walker learned from deposition testimony of LFM's office administrator). However, the Amended Complaint does not make any allegation that a physician assistant or nurse practitioner was employed at LFM prior to February 1997.

LFM were to bill the nurse practitioner and physician assistant services as independent services, "it could not afford to employ [Walker]." Amended Complaint ¶ 11. The same paragraph further alleges, "LFM's Medicare billing practices did not change subsequent to [Walker's] conversation with Gail Mayer." *Id.* Paragraph 9 of the Amended Complaint states, "Since [Walker's] employment with LFM, LFM has employed at least two more nurse practitioners and two more physician's assistants." Thus, the Amended Complaint does not limit the allegations of false claims to the time period during which Walker was employed by LFM. Rather, it alleges an ongoing practice of false billing from the time Walker began working as a nurse practitioner at LFM, in February 1997. The proper temporal range for discovery is February 1997 through the date of the original complaint.

C. The Denial of the Motion to Dismiss

Finally, LFM cross-appeals, arguing that the district court erred in denying LFM's Federal Rule of Civil Procedure 12(b)(6) motion to dismiss the Amended Complaint. The motion was grounded on the assertion that the Amended Complaint failed to plead fraud with particularity as required by Federal Rule of Civil Procedure 9(b). We find this argument meritless.

This is not a case like *United States ex rel. Clausen v. Laboratory Corporation of America, Inc.*, 290 F.3d 1301 (11th Cir. 2002), in which a "corporate outsider" made speculative assertions that claims "must have been submitted, were likely submitted or should have been submitted to the Government." 290 F.3d at 1311. Neither is this case like *Corsello v. Lincare, Inc.*, 428 F.3d 1008 (11th Cir. 2005), in which we recently affirmed the district court's dismissal on the ground that the relator's complaint was deficient under Rule 9(b) because it "failed to explain why he believe[d] fraudulent claims were ultimately submitted." 428 F.3d at 1014.

Walker's complaint identifies her as a nurse practitioner who was employed at LFM. Amended Complaint ¶7. Walker alleges that, during her employment at LFM, she never had her own UPIN and that she was instructed each day "which doctor she would be billing under." Amended Complaint ¶¶ 11, 15. The Amended Complaint also alleges that Walker had at least one personal discussion with LFM's office administrator (identified in the complaint by name) during which the two women discussed that Walker did not have her own UPIN, whether Walker and the other nurse practitioners and physician assistants should have their own UPINs, that (according to the office administrator) LFM billed all nurse practitioner and physician assistant services as rendered "incident to the service of a physician," that (also according to the office administrator) LFM had "never" billed nurse practitioner or physician assistant services in another manner, and the propriety of the billing method. Amended Complaint ¶¶ 10-12. These allegations are sufficient to explain why Walker believed LFM submitted false or fraudulent claims for services rendered by nurse practitioners and physician assistants "incident to the service of a physician." Therefore, we affirm the district court's order denying LFM's motion to dismiss Walker's complaint.

VI. CONCLUSION

For the reasons stated above, we reverse the grant of summary judgment in favor of R&F Properties of Lake County, Inc., formerly known as Leesburg Family Medicine. We find no error in the district court's denial of R&F Properties of Lake County, Inc.'s motion to dismiss the Amended Complaint. Finally, we conclude that the district court erred in limiting the temporal scope of discovery and remand for further proceedings consistent with this opinion.

REVERSED AND REMANDED.

Appendix B

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
OCALA DIVISION

UNITED STATES OF AMERICA
ex rel., KARYN L. WALKER,

Plaintiff,

-vs- Case No. 5:02-cv-131-Oc-10GRJ

R & F PROPERTIES OF LAKE COUNTY, INC.,

Defendant.

ORDER

This *qui tam* action is before the Court for consideration of "Defendant's Motion for Summary Final Judgment with Incorporated Memorandum of Law" (Doc. 72), to which the Plaintiff has responded (Doc. 79). For the reasons set forth below, the Court has concluded that the Defendant's motion is due to be granted.

BACKGROUND

On May 6, 2002 the Plaintiff filed this action pursuant to the federal False Claims Act, 31 U.S.C. § 3729 *et. seq.* The United States declined to intervene (Doc. 14). On September 19, 2003, the Court entered an Order (Doc. 36) denying the Defendant's "Motion to Dismiss the Plaintiff's Complaint for Failure to Plead Fraud with Particularity" (Doc. 23). On December 8, 2003, after the Court held that the Plaintiff's

discovery request for Medicare claims documents from the Defendant should be limited to documents for services performed by the Plaintiff and any other nurse practitioner (as distinguished from services provided by a physician assistant) employed by the Defendant during the time period in which the Plaintiff was employed, the Plaintiff filed an amended complaint (Doc. 52). The amended complaint contains essentially the same allegations as those contained in the previous complaint, but it now includes allegations as to the medical services provided by "a physician's assistant" and "other nurse practitioners" (compare Doc. 1 with Doc. 52). On April 21, 2004, the Court issued an Order (Doc. 64) denying in all respects the Defendant's "Motion to Dismiss [the Plaintiff's] Amended Complaint and, Alternatively, to Certify to the Eleventh Circuit the Controlling Question Concerning the Sufficiency of the Amended Complaint" (Doc. 58).

The facts, as set forth in the Plaintiff's amended complaint, are as follows. The Defendant, R & F Properties of Lake County, Inc., formerly known as Leesburg Family Medicine (LFM), provides general and family medical services in Leesburg and Lady Lake, Florida. A majority of the Defendant's patients are covered by Medicare, a federally funded health insurance program. The Plaintiff was employed by the Defendant as a nurse practitioner from February 1997 to May 1999. The Plaintiff worked Monday through Friday from 8:00 a.m. to 5:00 p.m., and beginning in or around May 1997, she also worked one evening per week from 5:00 p.m. to 8:00 p.m., during which time she would provide services for 15 to 20 patients, and one Saturday per month from 8:00 a.m. to 5:00 p.m., during which time she would see an average of 20 patients.

The Plaintiff alleges that for the first few weeks of her employment she would present every patient's care plan to a

physician and receive feedback with respect to each patient. After the first few weeks of her employment had passed, the Plaintiff states that she did not present every patient she treated to one of the Defendant's physicians; rather, the Plaintiff alleges that of all of the patients that she treated, she only presented the "more serious, complicated cases." In fact, the Plaintiff contends that during her evening shifts and Saturday shifts she provided medical services to patients without any physician on site. Thus, the Plaintiff asserts that she was the sole provider of medical services to a majority of her patients. Despite this, the Plaintiff alleges that her services as a nurse practitioner were billed to Medicare as "incident to" the care of one of the Defendant's physicians.

The Plaintiff also states that during the entire period of her employment, the Defendant employed a physician's assistant, who worked the same evening and Saturday shifts as the Plaintiff. The Plaintiff asserts that "the physician's assistant and other nurse practitioners also saw new patients, and saw existing patients with new complaints, changing the patients' treatment plans and made new diagnoses" (Doc. 52).

The Plaintiff claims that in order to properly bill services provided to a Medicare beneficiary by a Mid-Level Care Provider, such as a physician's assistant or nurse practitioner, as "incident to" the services of a physician, the following conditions must be met: (1) a physician must be on site; (2) the services must be provided to an established patient with a condition that has been previously addressed by a physician along with a treatment plan devised by the physician; (3) the services must be provided in a follow up visit to the original diagnosis with no new symptoms; (4) the services to an existing patient cannot change the treatment plan in place; and (5) the services to an existing patient cannot result in a new diagnosis. The Plaintiff claims that the Defendant knowingly presented to the United States Government false

and fraudulent claims for reimbursement by billing the Plaintiff's services as "incident to" a physician's services even though on many occasions a physician was not on site when she provided services, she would see existing patients and change their treatment plans or make new diagnoses, and she would see new patients and make initial diagnoses and treatment plans.

The Defendant claims "there is no disputed issue of material fact as to whether [the Defendant's] claims to Medicare were false or fraudulent" (Doc. 72). The Defendant argues that the conditions required to bill for services "incident to" the care of a physician, as alleged by the Plaintiff, are not applicable to the time in question because Medicare law and regulations did not require the fulfillment of such conditions and the Medicare Carriers Manual, which contained such conditions, lacked the force and effect of law. In response, the Plaintiff argues that the Defendant's Motion fails to address important allegations in this action, therefore any ruling on this Motion will not be dispositive of the entire case (Doc. 79).[1] Additionally, the Plaintiff argues that the fundamental question in this case is not whether the Carriers Manual has the force and effect of law, but whether the Defendant filed a false claim.

SUMMARY JUDGMENT STANDARD

Pursuant to Federal Rule of Civil Procedure 56(c), the entry of summary judgment is appropriate only when the Court is satisfied that "there is no genuine issue as to any

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[1] The Plaintiff claims that the Defendant's Motion fails to address the allegation that the Defendant knowingly and improperly made claims to Medicare under the "incident to" provision for nonphysician services that were not actually incidental to any treatment provided by a physician. However, the Defendant addresses this claim in Doc. 72, page 8.

material fact and that the moving party is entitled to a judgment as a matter of law." In Celotex Corp. v. Catrett, the Supreme Court recognized that "the plain language of Rule 56(c) mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial."[2] The moving party bears the initial burden of establishing the nonexistence of a triable fact issue. If the movant is successful on this score, the burden of production shifts to the non-moving party who must then come forward with "sufficient evidence of every element that he or she must prove."[3] The non-moving party may not simply rest on the pleadings, but must use affidavits, depositions, answers to interrogatories, or other admissible evidence to demonstrate that a material fact issue remains to be tried.[4]

DISCUSSION

The False Claims Act was initially enacted to address the widespread fraud associated with Civil War defense contracts.[5] At that time, it was clear that the False Claims Act "was not designed to reach every kind of fraud practiced on the Government."[6] In 1986, the Act was substantially amended to address fraud in the areas of defense and

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[2] 477 U.S. 317, 322 (1986).

[3] Rollins v. Techsouth, Inc., 833 F.2d 1525, 1528 (11th Cir. 1987).

[4] Celotex, 477 U.S. at 324.

[5] See United States v. McNinch, 356 U.S. 595, 599 (1958).

[6] Id.

healthcare.[7] The 1986 amendments to the False Claims Act "modernizes jurisdiction and venue provisions, increases recoverable damages, raises civil forfeiture and criminal penalties, defines the mental element required for a successful prosecution and clarifies the burden of proof in civil false claims actions."[8] In essence, the amendments provide the Government with "a more useful tool against fraud in modern times" and "encourage[s] any individual knowing of Government fraud to bring that information forward."[9] Nonetheless, the penal nature of the False Claims Act requires careful scrutiny of any alleged misconduct under the statute[10] and the Act should not be used to "police technical compliance with administrative regulations."[11]

To establish a cause of action under 31 U.S.C.A. § 3729(a) of the False Claims Act, the Plaintiff must prove at least three elements: (1) a "false or fraudulent" claim (2) which was presented, or caused to be presented, by the Defendant to the United States for payment or approval (3) with knowledge that the claim was false. The dispositive issue in this case on summary judgment is whether the Plaintiff has introduced sufficient evidence to establish that the claims presented to the Government by the Defendant were false.

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[7] See S.Rep. No. 99-345, at 2-4, 8 (1986); reprinted in 1986 U.S.C.C.A.H. 5266, 5267-69, 5273.

[8] Id. at 2.

[9] Id.

[10] See U.S. ex rel. Weinberger v. Equifax, Inc., 557 F.2d 456, 460 (5th Cir. 1977).

[11] U.S. ex rel. Lamers v. City of Green Bay, 168 F.3d 1013, 1020 (7th Cir. 1999).

The "false or fraudulent" element is not defined by the False Claims Act. But the Second Circuit has described "false" to mean "not true," "deceitful," or "tending to mislead," and has described "fraud" as an "intentional misrepresentation, concealment, or nondisclosure for the purpose of inducing another in reliance upon it to part with some valuable thing belonging to him or to surrender a legal right."[12] In addition, the terms "false or fraudulent" in the False Claims Act "suggest an improper claim is aimed at extracting money the government otherwise would not have paid."[13] The Second Circuit recognized that a false claim may take different forms: a claim may be "factually false" if it "involves an incorrect description of goods or services provided or a request for goods or services never provided" or "legally false" if "a party certifies compliance with a statute or regulation as a condition to governmental payment" and then violates the applicable law.[14] A review of the amended complaint reveals that the Plaintiff contends that the claims submitted for her services were either factually false or legally false or both. With respect to the factually false claims, the Plaintiff alleges that she and other nonphysicians provided specific services, without the aid, assistance, or supervision of a physician, and that such services were then billed by the Defendant as if they were provided under the care or supervision of a physician. With respect to the legally false claims, the Plaintiff alleges that the Defendant contravened Medicare statutes and regulations by billing her services, as well as other nonphysicians' services, as "incident to" the services of a physician.

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[12] Mikes v. Straus, 274 F.3d 687, 696 (2d Cir. 2001) (citations omitted).

[13] Id.

[14] Id. at 697.

Legally False Claims

The Court concludes that the Plaintiff has failed to produce sufficient evidence to establish that the Defendant presented legally false claims to the Government either by billing nonphysician services as "incident to" the care of a physician when no physician was on site, or by billing nonphysician services as "incident to" a physician's involvement when nonphysicians provided initial diagnoses or changed treatment plans. During the relevant time period, between 1997 and 1999, neither the Medicare statutes nor the regulations provided much guidance on the level of supervision required in order to bill the services of a nurse practitioner or physician assistant as "incident to."[15] Therefore, the Plaintiff relies on the Medicare Carriers Manual to prove that the Defendant presented legally false

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[15] Pursuant to 42 U.S.C. § 1395k(a)(2)(B), the benefits provided to an individual under the Medicare Part B insurance program, which is the voluntary insurance program created pursuant to 42 U.S.C. § 1395j to provide medical insurance benefits for aged and disabled individuals, consist of, *inter alia*, "entitlement to have payment made on his behalf . . . for medical and other services . . . furnished by a provider of services." The definition of the term "medical and other health care services" includes "services and supplies . . . furnished as an incident to a physician's professional service, of kinds which are commonly furnished in physicians' offices and are commonly either rendered without charge or included in the physicians' bills." 42 U.S.C. § 1395x(s)(2)(B) (emphasis added). The regulations promulgated by the Department of Health and Human Resources for the years 1997, 1998, and 1999 – the years of the Plaintiff's employment and the controlling years for this action – are equally unspecific in terms of defining "incident to." For example, 42 C.F.R. § 410.10(b) and 42 C.F.R. § 410.26(a) simply recite the language of 42 U.S.C. § 1395x(s)(2)(B).

claims.[16] The Court finds this evidence to be insufficient to withstand a motion for summary judgment because a failure to comply with the Carriers Manual guidelines does not sufficiently establish that the Defendant presented legally false claims to the Government.

According to the Centers for Medicare & Medicaid Services, or CMS, the entity within the Department of Health and Human Services charged with administering the Medicare program, the CMS program manuals "contain operating instructions, policies, and procedures based on

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[16] § 2050 of the Medicare Carriers Manual states that for services or supplies to be covered as "incident to the services of a physician, services and supplies must be: [a]n integral, although incidental, part of the physician's professional service (see § 2050.1); [c]ommonly rendered without charge or included in the physician's bill (see § 2050.1A); [o]f a type that are commonly furnished in physician's offices or clinics (see § 2050.1A); [f]urnished under the physician's direct personal supervision (see § 2050.1B); and [f]urnished by the physician or by an individual who qualifies as an individual of the physician. (See § 2050.1C)." § 2050.1 of the Carriers Manual further defines "Incident to Physician's Professional Services" as those services that are an "integral, although incidental, part of the physician's personal services in the course if diagnosis or treatment of an injury or illness." § 2050.1B of the Carriers Manual states "Direct Personal Supervision" means that "the physician must be present in the office suite and immediately available to provide assistance and direction throughout the time the aide is performing services."

§ 2050.2 describes the coverage available for the services of nonphysicians when they are furnished incident to a physician. In particular, the provision states that to have the service covered as incident to the services of a physician, "there must have been a direct, personal, professional service furnished by the physician to initiate the course of treatment of which the service being performed by the nonphysician practitioner is an incidental part . . ."

statutes and regulations, guidelines, models and directives."[17] CMS manuals address various topics and audiences, including hospitals, home health agencies, nursing facilities, intermediaries, carriers, and providers.[18] CMS defines a "carrier" as "a private company that has a contract with Medicare to pay your Medicare Part B bills."[19] In addition, CMS defines a "provider" as "[a]ny organization, institution, or individual that provides health care services to Medicare beneficiaries."[20] The Medicare Carriers Manual in particular "provides operating policies and procedures for contractors charged with administering the program . . . contains informational and procedural material the carrier needs for efficient processing and payment of claims . . . [and] includes instructions dealing with coverage of services, bill review, reasonable charges, and other pertinent claims procedures."[21]

The United States Supreme Court has held that the Medicare Provider Reimbursement Manual is an interpretive rule, which does not have the force and effect of law and is not accorded that weight in the adjudicatory process.[22] The Supreme Court has also held that "interpretations contained

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[17] Centers for Medicare & Medicaid Services, Medicare and Medicaid Paper-Based Manuals, at http://www.cms.hhs.gov/manuals/cmstoc.asp (last visited August 30, 2004).

[18] Id.

[19] Center for Medicare & Medicaid Services, Glossary, at http://www.cms.hhs.gov/glossary/default.asp?Letter=C&Language=English#Content (last visited August 30, 2004).

[20] Id.

[21] Centers for Medicare & Medicaid Services, Medicare and Medicaid Paper-Based Manuals, at http://www.cms.hhs.gov/manuals/cmstoc.asp (last visited August 30, 2004).

[22] Shalala v. Guernsey Memorial Hosp., 514 U.S. 87, 99 (1995).

in policy statements, agency manuals, and enforcement guidelines, all of which lack the force of law . . ." only warrant "some deference."[23] Consequently, the Carriers Manual, which is part of the same series of manuals issued by CMS as the Provider Reimbursement Manual, does not have the force and effect of law and should only be accorded some deference. Moreover, the Carriers Manual simply operates as a guideline for carriers in deciding whether or not to reimburse providers, it does not establish binding rules and regulations that providers must follow to avoid liability under the False Claims Act. Therefore, the Defendant in this case did not present a legally false or fraudulent claim to the Government by billing services as "incident to" the care of a physician solely because the Defendant contravened a manual that is directed toward carriers, not providers, and which should only be accorded "some deference."

The Plaintiff relies on In re Cardiac Devices Qui Tam[24] to establish that a violation of the Carriers Manual can result in liability under the False Claims Act. However, Cardiac Devices is distinguishable. The district court denied the defendants' motions to dismiss in that case because the defendant hospitals could face liability under the False Claims Act by violating provisions of the CMS Hospital Manual.[25] On the other hand, this case involves a motion for summary judgment on a claim that a provider failed to follow the guidelines set forth in a carriers manual.

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[23] Christensen v. Harris County, 529 U.S. 576, 587 (2000) (quoting EEOC v. Arabian Oil Co., 499 U.S. 244, 256-58 (1991)).

[24] 221 F.R.D. 318 (D. Conn. 2004).

[25] Id. at 353.

In United States ex rel. Swafford v. Borgess Medical Center, the plaintiff brought a claim under the False Claims Act against a group of doctors for improperly billing Medicare for venous ultrasound studies.[26] Like this case, the plaintiff relied on the Carriers Manual to establish that the doctors' claims were false.[27] The district court stated that the "Carriers Manual is merely a guide for fiscal intermediaries between Medicare and physicians, and lacks 'the binding effect of law or regulation' . . . Moreover, the Carriers Manual is intended to instruct carriers as to whether to play a claim and is not routinely provided to physicians."[28] In granting the defendant's motion for summary judgment, the district court "decline[d] to judge the truth or falsity of defendants' representations" based upon the Carriers Manual, which did not even "purport to address the physician's decision to submit a claim for reimbursement."[29]

The Plaintiff also argues that the Defendant presented legally false claims by violating an agreement with the Defendant's carrier, Blue Cross Blue Shield, and by not following the Medicare publications and training materials relating to "incident to" billing procedures. The Plaintiff alleges that the Defendant's agreement[30] with Blue Cross Blue Shield, which concerns the Defendant's submission of claims to Blue Cross Blue Shield via electronic media, establishes

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[26] 98 F. Supp. 2d 822, 825-26 (W.D. Mich. 2000), aff'd, 24 Fed. Appx. 491 (6th Cir. 2001), cert. denied, 535 U.S. 1096 (2002).

[27] Id.

[28] Id. at 828 (quoting in part National Medical Enterprises v. Bowen, 851 F.2d 291, 293 (9th Cir. 1988).

[29] Id.

[30] (Doc. 79, Exhibit A).

that the Defendant certified compliance with the Carriers Manual, thus making the Manual's "incident to" provisions applicable to the Defendant.[31] The Court finds this argument to be without merit. No where in the agreement does the Defendant explicitly agree to abide by the "incident to" provisions in the Carriers Manual, nor does the Defendant agree to comply with the entire manual to receive payment. The agreement simply states that payments may be adjusted according to the guidelines and the Defendant agrees to obtain the signature of each patient and use the signature in accordance with the guidelines.

Furthermore, the Plaintiff suggests that the Defendant can be held liable under the False Claims Act for not following Medicare publications[32] or training materials,[33] which state that a physician must be on site to bill services as "incident to" the care of a physician.[34] The Court concludes that the Defendant's apparent failure to follow these publications and training materials does not establish that the Defendant presented a legally false claim to the Government because not only do these materials lack the force and effect of law, but the Plaintiff has not presented any evidence that the Defendant agreed to comply with these materials in order to receive payment from the Government.[35]

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[31] (Doc. 79, page 4).

[32] (Doc. 79, Exhibit F).

[33] (Doc. 79, Exhibit D).

[34] (Doc. 79, page 5).

[35] See Mikes, 274 F.3d at 697, where the Second Circuit limited False Claims Act liability under a legally false claim certification theory to those situations where a party certifies compliance with the statute or regulation as condition of payment by the Government.

Consequently, the Medicare statutes, regulations, Carrier's Manual, and publications do not provide the plaintiff with sufficient evidence to support a finding that the Defendant presented legally false claims to the government.

Factually False Claims

The Plaintiff also alleges that the Defendant presented factually false claims by allowing the Plaintiff and other nonphysicians to render services, such as initial diagnoses and changed treatment plans, without the assistance of a physician and then bill such services as if they were under the care and supervision of a physician. The Court concludes that the plaintiff has also failed to introduce sufficient evidence to establish that the Defendant presented factually false claims by submitting an "incorrect description of goods or services provided" or making a claim for "services never provided."[36]

First, the Medicare insurance claim form used by the Defendant to submit claims simply states that

> [f]or services to be considered as "incident" to a physician's professional service, 1) they must be rendered under the physician's immediate personal supervision by his/or employee, 2) they must be an integral, although incidental part of a covered physician's service, 3) they must be of kinds commonly furnished in physician's offices, and 4) the services of nonphysicians must be included on the physician's bills.[37]

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[36] Id.

[37] See Health Insurance Claim Form, Form RRB-1500 (emphasis added).

The terms "immediate," "integral," and "incidental" are inherently imprecise and the Plaintiff has failed to present sufficient evidence that the Defendant's interpretation of the terms, that it was appropriate to have a physician immediately available by phone while treating patients or for nonphysicians to change treatment plans or offer diagnoses under the supervision of a physician, contravened the requirements of the form or the Medicare statutes and regulations, thus violating the False Claims Act.[38]

Second, Florida law supports a finding that the claims submitted by the Defendant were not factually false. Florida Statutes regulating the practice of medicine encourage physicians to more effectively utilize their specialized skills by "delegat[ing] health care tasks to qualified assistants when such delegation is consistent with the patient's health and welfare."[39] Moreover, Florida law defines "supervision" of a physician over his or her assistants as "responsible supervision and control" with "easy availability" to physician.[40] Florida law specifically establishes that the "term 'easy availability' includes the ability to communicate by way of telecommunication."[41] It is undisputed that the physicians

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[38] When statutes and regulations forming the basis of the Plaintiff's claims under the False Claims Act are ambiguous, the Plaintiff has the burden of proving that the statements made by the Defendant in presenting its claim for reimbursement were unreasonable. See, e.g., Luckey v. Baxter Healthcare Corp., 2 F. Supp. 2d 1034, 1049 (N.D. Ill. 1998).

[39] § 458.347(1)(a), Fla. Stat. (1997).

[40] § 458.347(2)(f), Fla. Stat. (1997).

[41] Id. See also, § 464.012(3), Fla. Stat. (1997), which sets forth the functions of nurse practitioners and Rule 64B9-4.001(14), Fla. Admin. Code (1999), which allows for nurse practitioners to perform procedures out of the presence of a physician as long as the practitioner can contact the physician by "communication devices."

in this case were always available by phone or pager to consult with the nurse practitioner or assistants on duty, as required by Florida law, thereby further supporting the finding that the Defendant did not submit factually false claims in this case.[42]

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[42] See Doc. 81, deposition of Karyn L. Walker.

CONCLUSION

Accordingly, upon due consideration, it is ordered:

(1) the Defendant's Motion for Summary Judgment (Doc. 72) is GRANTED.

(2) the Clerk is directed to enter judgment accordingly, terminate any pending motions, and close the files.

IT IS SO ORDERED.

DONE and ORDERED at Ocala, Florida this 6th day of October, 2004.

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United States District Judge

Copies to: Counsel of Record
Maurya McSheehy

Appendix C

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 04-15283

UNITED STATES, ex rel.,

Plaintiff,

KARYN L. WALKER,
a.k.a. Karyn L. Denk-Walker,

Plaintiff-Appellant
Cross-Appellee

Versus

R & F PROPERTIES OF LAKE COUNTY, INC.,
A Florida Professional Association,

Defendant-Appellee
Cross-Appellant.

On Appeal from the United States District Court for the
Middle District of Florida

ON PETITION(S) FOR REHEARING AND PETITION(S) FOR REHEARING EN BANC

Before: BIRCH, WILSON AND COX, Circuit Judges.

PER CURIAM:

The Petition(s) for Rehearing are DENIED and no Judge in regular active service on the Court having requested that the Court be polled on rehearing en banc (Rule 35, Federal Rules of Appellate Procedure), the Petition(s) for Rehearing En Banc are DENIED.

Appendix D

1. **Amendment V of the U.S. Constitution provides:**
Amendment V

No person shall be held to answer for a capital, or otherwise infamous crime, unless on a presentment or indictment of a grand jury, except in cases arising in the land or naval forces, or in the militia, when in actual service in time of war or public danger; nor shall any person be subject for the same offense to be twice put in jeopardy of life or limb; nor shall be compelled in any criminal case to be a witness against himself, nor be deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use, without just compensation.

2. **Section 286 of Title 18, U.S.C. provides:**
§ 286 (2006). Conspiracy to defraud the government with respect to claims

Whoever enters into any agreement, combination, or conspiracy to defraud the United States, or any department or agency thereof, by obtaining or aiding to obtain the payment or allowance of any false, fictitious or fraudulent claim, shall be fined under this title or imprisoned not more than ten years, or both.

3. **Section 287 of Title 18, U.S.C. provides:**
§ 287 (2006). False, fictitious or fraudulent claims

Whoever makes or presents to any person or officer in the civil, military, or naval service of the United States, or to any department or agency thereof, any claim upon or against the United States, or any department or agency thereof, knowing such claim to be false, fictitious, or fraudulent, shall be imprisoned not more than five years and shall be subject to a fine in the amount provided in this title.

4. Section 1001 of Title 18, U.S.C. provides:
§ 1001 (2006). Statements or entries generally

(a) Except as otherwise provided in this section, whoever, in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States, knowingly and willfully—

(1) falsifies, conceals, or covers up by any trick, scheme, or device a material fact;

(2) makes any materially false, fictitious, or fraudulent statement or representation; or

(3) makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry; shall be fined under this title, imprisoned not more than 5 years or, if the offense involves international or domestic terrorism (as defined in section 2331), imprisoned not more than 8 years, or both.

(b) Subsection (a) does not apply to a party to a judicial proceeding, or that party's counsel, for statements, representations, writings or documents submitted by such party or counsel to a judge or magistrate in that proceeding.

(c) With respect to any matter within the jurisdiction of the legislative branch, subsection (a) shall apply only to—

(1) administrative matters, including a claim for payment, a matter related to the procurement of property or services, personnel or employment practices, or support services, or a document required by law, rule, or regulation to be submitted to the Congress or any office or officer within the legislative branch; or

(2) any investigation or review, conducted pursuant to the authority of any committee, subcommittee, commission or office of the Congress, consistent with applicable rules of the House or Senate.

5. **Section 1002 of Title 18, U.S.C. provides:**
§ 1002 (2006). Possession of false papers to defraud United States

Whoever, knowingly and with intent to defraud the United States, or any agency thereof, possesses any false, altered, forged, or counterfeited writing or document for the purpose of enabling another to obtain from the United States, or from any agency, officer or agent thereof, any sum of money, shall be fined under this title or imprisoned not more than five years, or both.

6. **Section 3729 of Title 31, U.S.C. provides:**
§ 3729 (2006).

(a) **Liability for certain acts.**—Any person who—

(1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;

(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government;

(3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid;

(4) has possession, custody, or control of property or money used, or to be used, by the Government and, intending to defraud the Government or willfully to conceal the property, delivers, or causes

to be delivered, less property than the amount for which the person receives a certificate or receipt;

(5) authorized to make or deliver a document certifying receipt of property used, or to be used, by the Government and, intending to defraud the Government, makes or delivers the receipt without completely knowing that the information on the receipt is true;

(6) knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the Government, or a member of the Armed Forces, who lawfully may not sell or pledge the property; or

(7) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government,

is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person, except that if the court finds that—

(A) the person committing the violation of this subsection furnished officials of the United States responsible for investigating false claims violations with all information known to such person about the violation within 30 days after the date on which the defendant first obtained the information;

(B) such person fully cooperated with any Government investigation of such violation; and

> **(C)** at the time such person furnished the United States with the information about the violation, no criminal prosecution, civil action, or administrative action had commenced under this title with respect to such violation, and the person did not have actual knowledge of the existence of an investigation into such violation;

the court may assess not less than 2 times the amount of damages which the Government sustains because of the act of the person. A person violating this subsection shall also be liable to the United States Government for the costs of a civil action brought to recover any such penalty or damages.

(b) Knowing and knowingly defined.—For purposes of this section, the terms "knowing" and "knowingly" mean that a person, with respect to information—

> **(1)** has actual knowledge of the information;
>
> **(2)** acts in deliberate ignorance of the truth or falsity of the information; or
>
> **(3)** acts in reckless disregard of the truth or falsity of the information,

and no proof of specific intent to defraud is required.

(c) Claim defined.—For purposes of this section, "claim" includes any request or demand, whether under a contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States Government provides any portion of the money or property which is requested or demanded, or if the Government will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded.

(d) Exemption from disclosure.—Any information furnished pursuant to subparagraphs (A) through (C) of subsection (a) shall be exempt from disclosure under section 552 of title 5.

(e) Exclusion.—This section does not apply to claims, records, or statements made under the Internal Revenue Code of 1986.

7. **Section 3730 of Title 31, U.S.C. provides:**
§ 3730 (2006). Civil actions for false claims

(a) Responsibilities of the Attorney General.—The Attorney General diligently shall investigate a violation under section 3729. If the Attorney General finds that a person has violated or is violating section 3729, the Attorney General may bring a civil action under this section against the person.

(b) Actions by private persons.—

(1) A person may bring a civil action for a violation of section 3729 for the person and for the United States Government. The action shall be brought in the name of the Government. The action may be dismissed only if the court and the Attorney General give written consent to the dismissal and their reasons for consenting.

(2) A copy of the complaint and written disclosure of substantially all material evidence and information the person possesses shall be served on the Government pursuant to Rule 4(d)(4) of the Federal Rules of Civil Procedure. The complaint shall be filed in camera, shall remain under seal for at least 60 days, and shall not be served on the defendant until the court so orders. The Government may elect to intervene and proceed with the action

within 60 days after it receives both the complaint and the material evidence and information.

(3) The Government may, for good cause shown, move the court for extensions of the time during which the complaint remains under seal under paragraph (2). Any such motions may be supported by affidavits or other submissions in camera. The defendant shall not be required to respond to any complaint filed under this section until 20 days after the complaint is unsealed and served upon the defendant pursuant to Rule 4 of the Federal Rules of Civil Procedure.

(4) Before the expiration of the 60-day period or any extensions obtained under paragraph (3), the Government shall—

(A) proceed with the action, in which case the action shall be conducted by the Government; or

(B) notify the court that it declines to take over the action, in which case the person bringing the action shall have the right to conduct the action.

(5) When a person brings an action under this subsection, no person other than the Government may intervene or bring a related action based on the facts underlying the pending action.

(c) Rights of the parties to qui tam actions.—

(1) If the Government proceeds with the action, it shall have the primary responsibility for prosecuting the action, and shall not be bound by an act of the person bringing the action. Such person shall have the right to continue as a party to the action, subject to the limitations set forth in paragraph (2).

(2)

(A) The Government may dismiss the action notwithstanding the objections of the person initiating the action if the person has been notified by the Government of the filing of the motion and the court has provided the person with an opportunity for a hearing on the motion.

(B) The Government may settle the action with the defendant notwithstanding the objections of the person initiating the action if the court determines, after a hearing, that the proposed settlement is fair, adequate, and reasonable under all the circumstances. Upon a showing of good cause, such hearing may be held in camera.

(C) Upon a showing by the Government that unrestricted participation during the course of the litigation by the person initiating the action would interfere with or unduly delay the Government's prosecution of the case, or would be repetitious, irrelevant, or for purposes of harassment, the court may, in its discretion, impose limitations on the person's participation, such as—

(i) limiting the number of witnesses the person may call;

(ii) limiting the length of the testimony of such witnesses;

(iii) limiting the person's cross-examination of witnesses; or

(iv) otherwise limiting the participation by the person in the litigation.

(D) Upon a showing by the defendant that unrestricted participation during the course of the litigation by the person initiating the action would be for purposes of harassment or would cause the defendant undue burden or unnecessary expense, the court may limit the participation by the person in the litigation.

(3) If the Government elects not to proceed with the action, the person who initiated the action shall have the right to conduct the action. If the Government so requests, it shall be served with copies of all pleadings filed in the action and shall be supplied with copies of all deposition transcripts (at the Government's expense). When a person proceeds with the action, the court, without limiting the status and rights of the person initiating the action, may nevertheless permit the Government to intervene at a later date upon a showing of good cause.

(4) Whether or not the Government proceeds with the action, upon a showing by the Government that certain actions of discovery by the person initiating the action would interfere with the Government's investigation or prosecution of a criminal or civil matter arising out of the same facts, the court may stay such discovery for a period of not more than 60 days. Such a showing shall be conducted in camera. The court may extend the 60-day period upon a further showing in camera that the Government has pursued the criminal or civil investigation or proceedings with reasonable diligence and any proposed discovery in the civil action will interfere

with the ongoing criminal or civil investigation or proceedings.

(5) Notwithstanding subsection (b), the Government may elect to pursue its claim through any alternate remedy available to the Government, including any administrative proceeding to determine a civil money penalty. If any such alternate remedy is pursued in another proceeding, the person initiating the action shall have the same rights in such proceeding as such person would have had if the action had continued under this section. Any finding of fact or conclusion of law made in such other proceeding that has become final shall be conclusive on all parties to an action under this section. For purposes of the preceding sentence, a finding or conclusion is final if it has been finally determined on appeal to the appropriate court of the United States, if all time for filing such an appeal with respect to the finding or conclusion has expired, or if the finding or conclusion is not subject to judicial review.

(d) Award to qui tam plaintiff.—

(1) If the Government proceeds with an action brought by a person under subsection (b), such person shall, subject to the second sentence of this paragraph, receive at least 15 percent but not more than 25 percent of the proceeds of the action or settlement of the claim, depending upon the extent to which the person substantially contributed to the prosecution of the action. Where the action is one which the court finds to be based primarily on disclosures of specific information (other than information provided by the person bringing the action) relating to allegations or transactions in a

criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media, the court may award such sums as it considers appropriate, but in no case more than 10 percent of the proceeds, taking into account the significance of the information and the role of the person bringing the action in advancing the case to litigation. Any payment to a person under the first or second sentence of this paragraph shall be made from the proceeds. Any such person shall also receive an amount for reasonable expenses which the court finds to have been necessarily incurred, plus reasonable attorneys' fees and costs. All such expenses, fees, and costs shall be awarded against the defendant.

(2) If the Government does not proceed with an action under this section, the person bringing the action or settling the claim shall receive an amount which the court decides is reasonable for collecting the civil penalty and damages. The amount shall be not less than 25 percent and not more than 30 percent of the proceeds of the action or settlement and shall be paid out of such proceeds. Such person shall also receive an amount for reasonable expenses which the court finds to have been necessarily incurred, plus reasonable attorneys' fees and costs. All such expenses, fees, and costs shall be awarded against the defendant.

(3) Whether or not the Government proceeds with the action, if the court finds that the action was brought by a person who planned and initiated the violation of section 3729 upon which the action was brought, then the court may, to the extent the court

considers appropriate, reduce the share of the proceeds of the action which the person would otherwise receive under paragraph (1) or (2) of this subsection, taking into account the role of that person in advancing the case to litigation and any relevant circumstances pertaining to the violation. If the person bringing the action is convicted of criminal conduct arising from his or her role in the violation of section 3729, that person shall be dismissed from the civil action and shall not receive any share of the proceeds of the action. Such dismissal shall not prejudice the right of the United States to continue the action, represented by the Department of Justice.

(4) If the Government does not proceed with the action and the person bringing the action conducts the action, the court may award to the defendant its reasonable attorneys' fees and expenses if the defendant prevails in the action and the court finds that the claim of the person bringing the action was clearly frivolous, clearly vexatious, or brought primarily for purposes of harassment.

* * *

8. Section 3731 of Title 31, U.S.C. provides:
§ 3731 (2006). False claims procedure

(a) A subpena [sic] requiring the attendance of a witness at a trial or hearing conducted under section 3730 of this title may be served at any place in the United States.

(b) A civil action under section 3730 may not be brought—

(1) more than 6 years after the date on which the violation of section 3729 is committed, or

(2) more than 3 years after the date when facts material to the right of action are known or reasonably should have been known by the official of the United States charged with responsibility to act in the circumstances, but in no event more than 10 years after the date on which the violation is committed,

whichever occurs last.

(c) In any action brought under section 3730, the United States shall be required to prove all essential elements of the cause of action, including damages, by a preponderance of the evidence.

(d) Notwithstanding any other provision of law, the Federal Rules of Criminal Procedure, or the Federal Rules of Evidence, a final judgment rendered in favor of the United States in any criminal proceeding charging fraud or false statements, whether upon a verdict after trial or upon a plea of guilty or nolo contendere, shall estop the defendant from denying the essential elements of the offense in any action which involves the same transaction as in the criminal proceeding and which is brought under subsection (a) or (b) of section 3730.

9. **Section 3732 of Title 31, U.S.C. provides:**
§ 3732 (2006). False claims jurisdiction

(a) Actions under section 3730.—Any action under section 3730 may be brought in any judicial district in which the defendant or, in the case of multiple defendants, any one defendant can be found, resides, transacts business, or in which any act proscribed by section 3729 occurred. A summons as required by the Federal Rules of Civil Procedure shall be issued by the appropriate district court and served at any place within or outside the United States.

(b) Claims under state law.—The district courts shall have jurisdiction over any action brought under the laws of any State for the recovery of funds paid by a State or local government if the action arises from the same transaction or occurrence as an action brought under section 3730.

10. Section 410.10 of Title 42, C.F.R. provides:
§ 410.10 (2006). Medical and other health services: Included services.

Subject to the conditions and limitations specified in this subpart, "medical and other health services" includes the following services:

(a) Physicians' services.

(b) Services and supplies furnished incident to a physician's professional services, of kinds that are commonly furnished in physicians' offices and are commonly either furnished without charge or included in the physicians' bills.

(c) Services and supplies, including partial hospitalization services, that are incident to physician services and are furnished to outpatients by or under arrangements made by a hospital or a CAH.

(d) Diagnostic services furnished to outpatients by or under arrangements made by a hospital or CAH if the services are services that the hospital or CAH ordinarily furnishes to its outpatients for diagnostic study.

(e) Diagnostic laboratory and X-ray tests (including diagnostic mammography that meets the conditions for coverage specified in § 410.34(b) of this subpart) and other diagnostic tests.

(f) X-ray therapy and other radiation therapy services.

(g) Medical supplies, appliances, and devices.

(h) Durable medical equipment.

(i) Ambulance services.

(j) Rural health clinic services.

(k) Home dialysis supplies and equipment; on or after July 1, 1991, epoetin (EPO) for home dialysis patients, and, on or after January 1, 1994, for dialysis patients, competent to use the drug; self-care home dialysis support services; and institutional dialysis services and supplies.

(l) Pneumococcal vaccinations.

(m) Outpatient physical therapy and speech pathology services.

(n) Cardiac pacemakers and pacemaker leads.

(o) Additional services furnished to enrollees of HMOs or CMPs, as described in § 410.58.

(p) Hepatitis B vaccine.

(q) Blood clotting factors for hemophilia patients competent to use these factors without medical or other supervision.

(r) Screening mammography services.

(s) Federally qualified health center services.

(t) Services of a certified registered nurse anesthetist or an anesthesiologist's assistant.

(u) Prescription drugs used in immunosuppressive therapy.

(v) Clinical psychologist services and services and supplies furnished as an incident to the services of a clinical psychologist, as provided in § 410.71.

(w) Clinical social worker services, as provided in § 410.73.

(x) Services of physicians and other practitioners furnished in or at the direction of an IHS or Indian tribal hospital or clinic.

(y) Intravenous immune globulin administered in the home for the treatment of primary immune deficiency diseases.

11. Section 410.26 of Title 42, C.F.R. provided: § 410.26 (2001). Medical and other health services: Included services.

Subject to the conditions and limitations specified in this subpart, "medical and other health services" includes the following services:

(a) Physicians' services.

(b) Services and supplies furnished incident to a physician's professional services, of kinds that are commonly furnished in physicians' offices and are commonly either furnished without charge or included in the physicians' bills.

(c) Services and supplies, including partial hospitalization services, that are incident to physician services and are furnished to outpatients by or under arrangements made by a hospital or a CAH.

(d) Diagnostic services furnished to outpatients by or under arrangements made by a hospital or CAH if the services are services that the hospital or CAH ordinarily furnishes to its outpatients for diagnostic study.

(e) Diagnostic laboratory and X-ray tests (including diagnostic mammography that meets the conditions for coverage specified in § 410.34(b) of this subpart) and other diagnostic tests.

(f) X-ray therapy and other radiation therapy services.

(g) Medical supplies, appliances, and devices.

(h) Durable medical equipment.

(i) Ambulance services.

(j) Rural health clinic services.

(k) Home dialysis supplies and equipment; on or after July 1, 1991, epoetin (EPO) for home dialysis patients, and, on or after January 1, 1994, for dialysis patients, competent to use the drug; self-care home dialysis support services; and institutional dialysis services and supplies.

(l) Pneumococcal vaccinations.

(m) Outpatient physical therapy and speech pathology services.

(n) Cardiac pacemakers and pacemaker leads.

(o) Additional services furnished to enrollees of HMOs or CMPs, as described in § 410.58.

(p) Hepatitis B vaccine.

(q) Blood clotting factors for hemophilia patients competent to use these factors without medical or other supervision.

(r) Screening mammography services.

(s) Federally qualified health center services.

(t) Services of a certified registered nurse anesthetist or an anesthesiologist's assistant.

(u) Prescription drugs used in immunosuppressive therapy.

(v) Clinical psychologist services and services and

supplies furnished as an incident to the services of a clinical psychologist, as provided in § 410.71.

(w) Clinical social worker services, as provided in § 410.73.

(x) Services of physicians and other practitioners furnished in or at the direction of an IHS or Indian tribal hospital or clinic.

(y) Intravenous immune globulin administered in the home for the treatment of primary immune deficiency diseases.

12. Section 410.26 of Title 42, C.F.R. provides:
§ 410.26 (2006). Services and supplies incident to a physician's professional service: Conditions.

(a) Definitions. For purposes of this section, the following definitions apply:

(1) Auxiliary personnel means any individual who is acting under the supervision of a physician (or other practitioner), regardless of whether the individual is an employee, leased employee, or independent contractor of the physician (or other practitioner) or of the same entity that employs or contracts with the physician (or other practitioner).

(2) Direct supervision means the level of supervision by the physician (or other practitioner) of auxiliary personnel as defined in § 410.32(b)(3)(ii).

(3) Independent contractor means an individual (or an entity that has hired such an individual) who performs part-time or full-time work for which the individual (or an entity that has hired such an individual) receives an IRS-1099 form.

(4) Leased employment means an employment relationship that is recognized by applicable State law and that is established by two employers by a contract such that one employer hires the services of an employee of the other employer.

(5) Noninstitutional setting means all settings other than a hospital or skilled nursing facility.

(6) Practitioner means a non-physician practitioner who is authorized by the Act to receive payment for services incident to his or her own services.

(7) Services and supplies means any services or supplies (including drugs or biologicals that are not usually self-administered) that are included in section 1861(s)(2)(A) of the Act and are not specifically listed in the Act as a separate benefit included in the Medicare program.

(b) Medicare Part B pays for services and supplies incident to the service of a physician (or other practitioner).

(1) Services and supplies must be furnished in a noninstitutional setting to noninstitutional patients.

(2) Services and supplies must be an integral, though incidental, part of the service of a physician (or other practitioner) in the course of diagnosis or treatment of an injury or illness.

(3) Services and supplies must be commonly furnished without charge or included in the bill of a physician (or other practitioner).

(4) Services and supplies must be of a type that are commonly furnished in the office or clinic of a physician (or other practitioner).

(5) Services and supplies must be furnished under the direct supervision of the physician (or other

practitioner). The physician (or other practitioner) directly supervising the auxiliary personnel need not be the same physician (or other practitioner) upon whose professional service the incident to service is based.

(6) Services and supplies must be furnished by the physician, practitioner with an incident to benefit, or auxiliary personnel.

(7) A physician (or other practitioner) may be an employee or an independent contractor.

(c) Limitations.

(1) Drugs and biologicals are also subject to the limitations specified in § 410.29.

(2) Physical therapy, occupational therapy and speech-language pathology services provided incident to a physician's professional services are subject to the provisions established in § 410.59(a)(3)(iii), § 410.60(a)(3)(iii), and § 410.62(a)(3)(ii).

13. Section 410.32 of Title 42, C.F.R. provides:
§ 410.32 (2006). Diagnostic X-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

* * *

(b) Diagnostic x-ray and other diagnostic tests —

(1) Basic rule. Except as indicated in paragraph (b)(2) of this section, all diagnostic x-ray and other diagnostic tests covered under section 1861(s)(3) of the Act and payable under the physician fee schedule must be furnished under the appropriate level of supervision by a physician as defined in section 1861(r) of the Act. Services furnished without the

required level of supervision are not reasonable and necessary (see § 411.15(k)(1) of this chapter).

(2) Exceptions. The following diagnostic tests payable under the physician fee schedule are excluded from the basic rule set forth in paragraph (b)(1) of this section:

(i) Diagnostic mammography procedures, which are regulated by the Food and Drug Administration.

(ii) Diagnostic tests personally furnished by a qualified audiologist as defined in section 1861(ll)(3) of the Act.

(iii) Diagnostic psychological testing services when —

(A) Personally furnished by a clinical psychologist or an independently practicing psychologist as defined in program instructions; or

(B) Furnished under the general supervision of a physician or a clinical psychologist.

(iv) Diagnostic tests (as established through program instructions) personally performed by a physical therapist who is certified by the American Board of Physical Therapy Specialties as a qualified electrophysiologic clinical specialist and permitted to provide the service under State law.

(v) Diagnostic tests performed by a nurse practitioner or clinical nurse specialist authorized to perform the tests under applicable State laws.

(vi) Pathology and laboratory procedures listed in the 80000 series of the Current Procedural Terminology published by the American Medical Association.

(3) Levels of supervision. Except where otherwise indicated, all diagnostic x-ray and other diagnostic tests subject to this provision and payable under the physician fee schedule must be furnished under at least a general level of physician supervision as defined in paragraph (b)(3)(i) of this section. In addition, some of these tests also require either direct or personal supervision as defined in paragraphs (b)(3)(ii) or (b)(3)(iii) of this section, respectively. (However, diagnostic tests performed by a physician assistant (PA) that the PA is legally authorized to perform under State law require only a general level of physician supervision.) When direct or personal supervision is required, physician supervision at the specified level is required throughout the performance of the test.

(i) General supervision means the procedure is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure. Under general supervision, the training of the nonphysician personnel who actually perform the diagnostic procedure and the maintenance of the necessary equipment and supplies are the continuing responsibility of the physician.

(ii) Direct supervision in the office setting means the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean

that the physician must be present in the room when the procedure is performed.

(iii) Personal supervision means a physician must be in attendance in the room during the performance of the procedure.

* * *

14. Section 489.11 of Title 42, C.F.R. provides:
§ 489.11

(a) Action by CMS. If CMS determines that the provider meets the requirements, it will send the provider—

(1) Written notice of that determination; and

(2) Two copies of the provider agreement.

(b) Action by provider. If the provider wishes to participate, it must return both copies of the agreement, duly signed by an authorized official, to CMS, together with a written statement indicating whether it has been adjudged insolvent or bankrupt in any State or Federal court, or whether any insolvency or bankruptcy actions are pending.

(c) Notice of acceptance. If CMS accepts the agreement, it will return one copy to the provider with a written notice that—

(1) Indicates the dates on which it was signed by the provider's representative and accepted by CMS; and

(2) Specifies the effective date of the agreement.